DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-810/S-073

AstraZeneca LP
Attention: Gary P. Horowitz, Ph.D.
725 Chesterbrook Blvd.
Mailstop: E-3C
Wayne, PA 19087-5677

Dear Dr. Horowitz:

Please refer to your supplemental new drug application dated May 2, 2000, received May 3, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec (omeprazole) Delayed-Release Capsules.

We acknowledge receipt of your submissions dated March 14 and September 21, 2001. Your submission of September 21, 2001 constituted a complete response to our September 14, 2001 action letter.

This supplemental new drug application provides for revision of the **PRECAUTIONS, Information for Patients** and the **DOSAGE AND ADMINISTRATION** sections of the package insert to add information regarding the administration of the enteric-coated pellets in applesauce for patients who may have difficulty swallowing whole capsules.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert submitted September 21, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Maria R. Walsh, M.S., Project Manager, at (301) 443-8017.

Sincerely,

*{See appended electronic signature page}*

Victor F. C. Raczkowski, M.D., M.Sc.
Acting Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/
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Victor Raczkowski
10/30/01 11:14:40 AM